

**Amendments to the Claims:**

This listing of claims will replace all prior versions, and listings, of claims in the application:

**Listing of Claims:**

1 (currently amended). A method of aiding in a renal cell carcinoma prognosis, the method comprising:

(a) quantifying, by immunohistochemical staining or immunoassay, **expressed expression of the** human carbonic anhydrase IX (CAIX) protein **of SEQ ID NO:2**, if any, present in one or more samples derived from a renal tumor and/or a metastatic lesion derived from a renal tumor of a human subject diagnosed with **locally advanced or metastatic** renal clear cell carcinoma to produce quantified CAIX expression data indicating the overall quantification percentage of the sample(s) positive for CAIX expression;

(b) **obtaining a prognosis for the subject by** correlating the quantified CAIX expression data with a probability of a renal cell carcinoma prognosis ~~for the subject~~, wherein a quantification percentage of about 85% stratifies the prognosis ~~for the subject~~ with a quantification percentage lower than about 85% predicting a worse outcome for a subject with locally advanced renal clear cell cancer and poor survival for a subject with metastatic renal clear cell cancer; **and**

**(c) using the prognosis in the selection and design of a treatment regimen for the subject.**

2 (canceled).

3 (canceled).

4 (canceled).

5 (original). The method of claim 1, wherein the expressed CAIX are quantified by

immunohistochemical staining.

6 (canceled).

7 (original). The method of claim 1, wherein the quantified CAIX expression data comprises a quantification percentage of more than 85%, which quantification percentage correlates with a better prognosis for the subject than a quantification percentage of 85% or less when the subject is diagnosed with metastatic renal cell carcinoma.

8 (original). The method of claim 1, wherein the quantified CAIX expression data comprises a quantification percentage of 85% or less, which quantification percentage correlates with a better prognosis for the subject than a quantification percentage of 85% or less when the subject is diagnosed with non-metastatic renal cell carcinoma of T stage  $\geq 3$  and Fuhrman grade  $\geq 2$ .

9 (original). The method of claim 1, wherein the quantified CAIX expression data comprises a quantification percentage of more than 85%, which quantification percentage further correlates with a likely positive response to interleukin-2 immunotherapy for the subject.

10 (original). The method of claim 1, wherein the quantified CAIX expression data comprises a quantification percentage of more than 85%, which quantification percentage further correlates with a likely positive response to one or more CAIX-targeted therapies for the subject.

11 (original). The method of claim 1, wherein the quantified CAIX expression data comprises a quantification percentage of 85% or less, which quantification percentage further correlates with a likely positive response to an adjuvant immunotherapy for the subject when the subject is diagnosed with non-metastatic renal cell carcinoma of T stage  $\geq 3$  and Fuhrman grade  $\geq 2$ .

12 (original). The method of claim 1, wherein the quantified CAIX expression data are in a

computer-readable form.

13 (original). The method of claim 12, wherein (b) comprises operating a programmable computer that comprises at least one database and executing an algorithm that determines closeness-of-fit between the computer-readable quantified CAIX expression data and database entries, which entries correspond to clinical and/or pathological data for a population of renal cell carcinoma patients to thereby correlate the quantified CAIX expression data with the probability of the renal cell carcinoma prognosis for the subject.

14 (currently amended). A method of aiding in a renal clear cell carcinoma prognosis, the method comprising:

(a) quantifying, by immunohistochemical staining or immunoassay using antibodies immunoreactive with a protein of SEQ ID NO:2, expressed CAIX polypeptides, if any, present in one or more samples derived from a human subject diagnosed with renal clear cell carcinoma to produce quantified CAIX polypeptide expression data, wherein the samples are derived from a renal tumor and/or a metastatic lesion derived from a renal tumor, and the quantified CAIX polypeptide expression data indicates the overall quantification percentage of the sample(s) positive for expression of the CAIX polypeptide; and,

(b) obtaining a prognosis for the subject by correlating the quantified CAIX polypeptide expression data with a probability of a renal clear cell carcinoma prognosis wherein a quantification percentage of about 85% stratifies the prognosis for the subject, wherein the prognosis for a subject having a sample quantification percentage below about 85% is worse than the prognosis for a subject having a higher sample quantification percentage; and

(c) using the prognosis in the selection and design of a treatment regimen for the subject.

15 (original). The method of claim 14, wherein the expressed CAIX polypeptides are quantified by immunohistochemical staining and the quantification percentage comprises a positive staining

percentage.

16 (original). The method of claim 14, wherein a quantification percentage of more than 85% correlates with a better prognosis for the subject than a quantification percentage of 85% or less when the subject is diagnosed with metastatic renal clear cell carcinoma.

17 (original). The method of claim 14, wherein a quantification percentage of more than 85% correlates with a better prognosis for the subject than a quantification percentage of 85% or less when the subject is diagnosed with non-metastatic renal clear cell carcinoma of T stage  $\geq 3$  and Fuhrman grade  $\geq 2$ .

18 (original). The method of claim 14, wherein a quantification percentage of more than 85% for a sample derived from the renal tumor correlates with a lower probability of metastasis than a quantification percentage of 85% or less for the sample derived from the renal tumor.

19 (original). The method of claim 14, wherein a quantification percentage of more than 85% further correlates with a likely positive response to interleukin-2 immunotherapy for the subject.

20 (original). The method of claim 14, wherein a quantification percentage of more than 85% further correlates with a likely positive response to one or more CAIX-targeted therapies for the subject.

21 (original). The method of claim 14, wherein a quantification percentage of 85% or less further correlates with a likely positive response to an adjuvant immunotherapy for the subject when the subject is diagnosed with non-metastatic renal cell carcinoma of T stage  $\geq 3$  and Fuhrman grade  $\geq 2$ .

22 (original). The method of claim 14, wherein the quantified CAIX expression data are in a

computer-readable form.

23 (original). The method of claim 22, wherein (b) comprises operating a programmable computer that comprises at least one database and executing an algorithm that determines closeness-of-fit between the computer-readable quantified CAIX expression data and database entries, which entries correspond to clinical and/or pathological data for a population of renal clear cell carcinoma patients to thereby correlate the quantified CAIX expression data with the probability of the renal clear cell carcinoma prognosis for the subject.

24 (canceled)

25 (canceled).

26 (previously presented). The method of claim 1, wherein the quantifying by immunohistochemistry uses antibodies immunoreactive with a protein of SEQ ID NO:2 to quantify the expressed CAIX protein.

27 (new). The method of claim 1, wherein the subject has localized renal cell cancer and a predicted worse outcome and the selected and designed treatment regimen is an adjuvant immunotherapy treatment regimen.

28. (new) The method of claim 14, wherein the subject has localized renal cell cancer and has a sample quantification percentage below about 85% and the selected and designed treatment regimen is an adjuvant immunotherapy treatment regimen.